

d.) **Remarks**

Applicant has amended claim 16 and added new claims 44-49. Support for the new claims can be found in original claims 16-19 and throughout the specification. No new matter is added. Accordingly, claims 1-49 are presently pending.

Remarks Regarding 35 U.S.C. § 112, Second Paragraph

Claims 16-20 stand rejected, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

First, claim 16 is alleged to read on a product of nature. Applicant respectfully disagrees. Claim 16 is directed to a diagnostic kit. A diagnostic kit, what ever it may contain, is not a product of nature. This aspect of the rejection is in error.

Second, the examiner indicates that the phrase “specifically binds” is preferred as compared to the phrase “specifically reactive.” This does not appear to be a part of the rejection, but a comment by the examiner. However, it is not understand what is meant by the term “preferred.” Clarification is requested.

Lastly, clarification is requested because it is alleged that the invention is directed to antibodies that bind to E1A antigen whereas claim 16 encompasses antibodies that can bind any one of *B. anthracis*, *B. thuringiensis* or *B. cereus*. Applicant respectfully disagrees.

Original claim 16 is directed to a diagnostic kit comprising an antibody that is specifically reactive against spores or vegetative cells of *B. anthracis*, *B. thuringiensis* or *B. cereus*. Accordingly, this claim is very clear. Again clarification of the examiner’s comments is requested.

Thus, in view of applicant’s remarks the rejection of claims 16-20, under 35 U.S.C. § 112, second paragraph, is in error or overcome and applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 112, First Paragraph

Claim 20 stands rejected, under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. Applicant respectfully traverses this rejection.

Claim 20 is alleged to encompass a kit that comprises antibodies that are specifically reactive against spores of *B. anthracis* and *B. thuringiensis* however the specification is alleged to be enabled for only antibodies to *B. anthracis*. Applicant respectfully disagrees.

Kits for the detection of Bacillus species of interest, such as *B. anthracis*, *B. anthracis* and *B. thuringiensis* are disclosed in the specification as well as methods for making Bacillus specific antibodies. For example, applicant discloses various types of diagnostic kits for the detection of various species of Bacillus (see specification at page 7, line 27 to page 9, line 7). Methods for producing antibodies that are useful in such kits are disclosed in the specification at page 6, line 14, to page 7, line 26.

In addition, the examiner states that it would require undue experimentation to identify epitopes unique to one species of Bacillus. Applicant respectfully disagrees and notes that the invention does not require the identification of unique epitopes. Applicant also respectfully notes that the specification provides significant and specific guidance as to how one of ordinary skill in the art is to create antibodies to a desired species of Bacillus. As discussed in depth therein:

“... This stimulates clones that haven’t already been stimulated by the antigenically similar boost, the specific clones. These species-specific clone should be maximally susceptible to being fused three days later. Thus, the number of cross-reacting clones should be greatly reduced or eliminated in the fusion products and a species-specific monoclonal antibody should be favored.” (see specification, page 7, lines 2-9).

No more is required under § 112.

Further, the examiner repeatedly states that no examples for the production of antibodies specifically reactive against species of Bacillus other than *B. anthracis* are disclosed. Applicant respectfully notes that the invention is not limited to the disclosures of the examples section, but encompasses the fullest extent of the disclosures of the entire specification including the background, the summary, the description of the invention, the examples, the claims and the figures. Again, no more is required under § 112 and, thus, the invention of claim 20 is fully enabled.

Thus, in view of applicant's remarks the rejection of claim 20, under 35 U.S.C. § 112, first paragraph, is overcome and applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 102(a)

Claims 16-19 stand rejected, under 35 U.S.C. § 102(a), as allegedly anticipated by Long et al. ("Long"). Applicant respectfully traverses this rejection.

It is alleged that Long teaches an antibody-based system for the detection of *B. anthracis* in environmental samples. Applicant respectfully asserts that Long is not enabled. However, claim 16 has been amended to recite that the diagnostic kit detects *B. anthracis* and not *B. thuringiensis*. Antibodies that detect *B. anthracis* and not *B. thuringiensis* are not disclosed or suggested in Long. Thus this rejection is moot.

Thus, in view of applicant's remarks the rejection of claims 16-19, under 35 U.S.C. § 102(a), is overcome and applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 102(b)

A. Claim 16 stands rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by Mesnage et al. ("Mesnage"). Applicant respectfully traverses this rejection.

Claim 16 has been amended to recite that the diagnostic kit detects *B. anthracis* and not *B. thuringiensis*. Antibodies that detect *B. anthracis* and not *B. thuringiensis* are not disclosed or suggested in Mesnage. Thus this rejection is moot.

Thus, in view of applicant's remarks the rejection of claim 16, under 35 U.S.C. § 102(b), is overcome and applicant respectfully requests that it be withdrawn.

B. Claim 16 stands rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by Phillips et al. ("Phillips"). Applicant respectfully traverses this rejection.

Claim 16 has been amended to recite that the diagnostic kit detects *B. anthracis* and not *B. thuringiensis*. Antibodies that detect *B. anthracis* and not *B. thuringiensis* are not disclosed or suggested in Phillips. Thus this rejection is moot.

Thus, in view of applicant's remarks the rejection of claim 16, under 35 U.S.C. § 102(b), is overcome and applicant respectfully requests that it be withdrawn.

C. Claim 16 stands rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by Wright et al. ("Wright"). Applicant respectfully traverses this rejection.

Claim 16 has been amended to recite that the diagnostic kit detects *B. anthracis* and not *B. thuringiensis*. Antibodies that detect *B. anthracis* and not *B. thuringiensis* are not disclosed or suggested in Wright. Thus this rejection is moot.

Thus, in view of applicant's remarks the rejection of claim 16, under 35 U.S.C. § 102(b), is overcome and applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 103(a)

A. Claims 16-20 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Kearney et al. ("Kearney") in view of Loomis et al. ("Loomis"). Applicant respectfully traverses this rejection.

It is alleged that Kearney teaches monoclonal antibodies that are specifically reactive to spores from different species of *Bacillus*. Example 13 is alleged to teach monoclonal antibodies that specifically react with *B. anthracis*, but not all react with *B. subtilis* or *B. thuringiensis*. Applicant respectfully disagrees.

Example 13 discloses an experiment whereby mice were immunized with heavily irradiated *B. anthracis* spores of two different strains. The authors conclude from FACS analysis that the resulting antibodies are not all reactive with *B. subtilis* or *B. thuringiensis*. Applicant respectfully disagrees. FACS analysis, as disclosed in Kearney, is insufficient to determine if the antibodies produced are specifically reactive to *B. anthracis*, but not reactive to *B. thuringiensis*, as recited in claim 16. FACS analysis therein shows that a profile is different, but that profile appears to overlap and further, that profile does not identify a single antibody. Accordingly, Kearney neither discloses or suggests an antibody that specifically reacts with *B. anthracis* but not *B. thuringiensis*, and the combination of Kearney in view of Loomis does not suggest applicant's claimed invention.

Thus, the rejection of claims 16-20, under 35 U.S.C. § 103(a), is overcome and applicant respectfully requests that it be withdrawn.

B. Claims 17-19 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Mesnage in view of Loomis. Applicant respectfully traverses this rejection.

Claims 17-19 are dependent from independent claim 16, which is allowable over the prior art. However applicant respectfully notes that the combination of Mesnage and Loomis does not disclose or suggest a diagnostic kit that is specifically reactive against spores of *B. anthracis* and not *B. thuringiensis*, which is in part the subject of original claim 19. Thus this rejection is in error, but now moot.

Thus, in view of applicant's remarks the rejection of claims 17-19, under 35 U.S.C. § 103(a), is overcome and applicant respectfully requests that it be withdrawn.

Remarks Regarding Prior Restriction Requirement

Applicant respectfully notes that the above rejections appear to have been made based on antibodies of the invention and not the invention of claims 16-20, namely diagnostic kits. In other words, the prior Restriction Requirement to kits is being ignored in favor of an analysis based solely on antibodies. Thus, applicant respectfully requests that the Restriction Requirement previously imposed on applicant be withdrawn and that all claims be examined in this application.

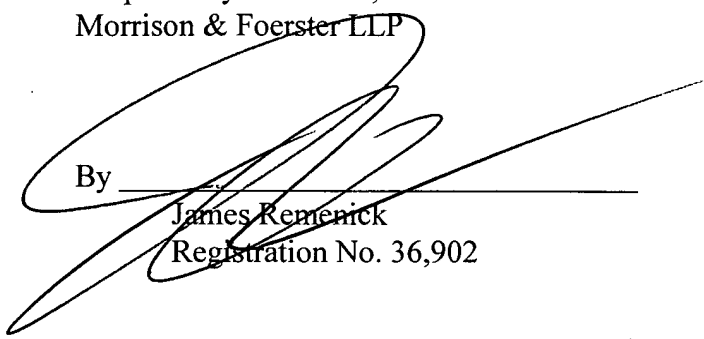
Conclusion

The application is in condition for allowance and the prompt issuance of a Notice of Allowance is respectfully requested. If there are any additional fees due with the filing of this Response, including any additional fees for a further extension of time, not herein accounted for, applicant respectfully requests that extension and also requests that any and all fees due be charged to Deposit Account No. 03-1952.

Respectfully submitted,
Morrison & Foerster LLP

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By


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